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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/399,083	09/17/1999	DAVID CALDERWOOD	BBI-6043CCPCPA	1842

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EXAMINER

RAO, DEEPAK R

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 09/26/2003

34

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/399,083

Applicant(s)
Calderwood et al.

Examiner
Deepak Rao

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 11, 2003
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 11, and 46-52 ☒ are pending in the application.
- 4a) Of the above, claim(s) 11 and 48-51 ☒ are withdrawn from consideration.
- 5) ☒ Claim(s) 52 ☒ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 46, and 47 ☒ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

This office action is in response to the amendment filed on July 11, 2003.

Claims 1-8, 10-11 and 46-52 are pending in this application.

Applicant is reminded that the examination is based on the elected species (as indicated in previous office actions) which reads on claims 1-8, 10, 46, 47 and 52. Claims 11 and 48-51 are withdrawn from further consideration as being drawn to nonelected species (see MPEP §803.02) pursuant to 37 CFR 1.142(b). Claims 1-8, 10, 46, 47 and 52 are considered to the extent readable on the examined subgenus, i.e., structural formula of claim 1 wherein ring A is phenyl; L is -NH-SO₂-; j is 0; R₃ is substituted phenyl; R₂ is H; and R₁ is cyclopentyl, and all other definitions of the variables and the other species are withdrawn from consideration as being drawn to nonelected species.

The following rejections are withdrawn:

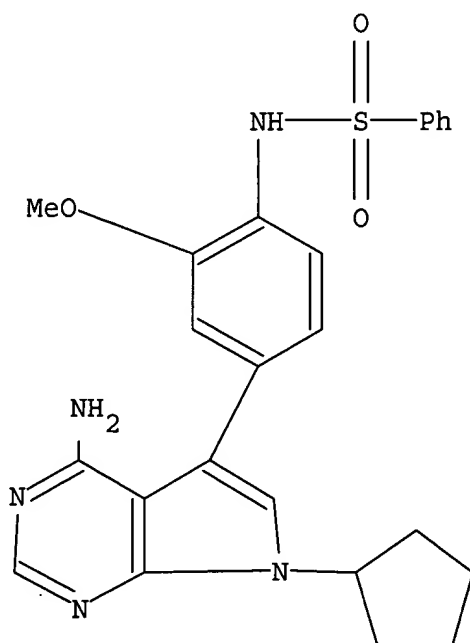
1. The terminal disclaimer filed on July 11, 2003 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,001,839 has been reviewed and is accepted. The terminal disclaimer has been recorded. The obviousness-type double patenting rejection has been withdrawn in view of the terminal disclaimer.
2. The rejections under 35 U.S.C. 112, second paragraph of the previous office action are withdrawn in view of the amendments.

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The following rejections are maintained:

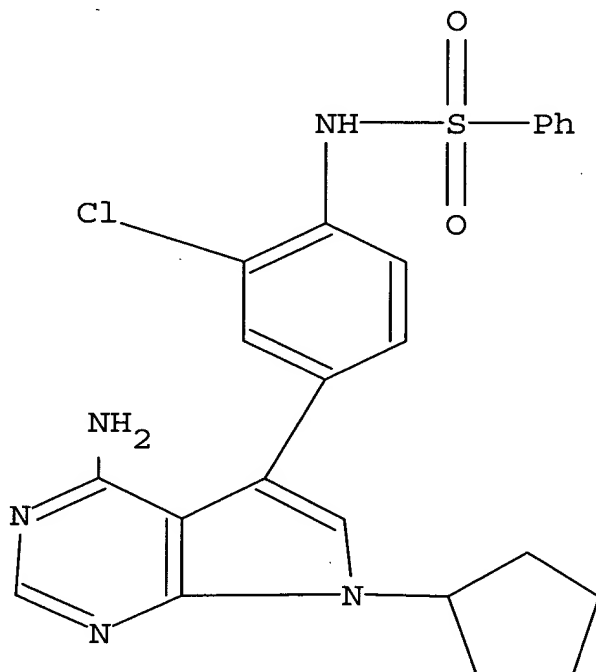
1. Claim 46 is rejected under 35 U.S.C. 103(a) over Calderwood et al., WO 98/41525, for the reasons provided in the previous office actions which are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that a prima facie case of obviousness has not been established because the reference does not teach or suggest all of the claim limitations. This is not found to be persuasive because the reference clearly teaches 4-amino-7H-pyrrolo[2,3-d]pyrimidin-5-yl compounds having an optionally substituted phenyl ring (wherein the optional substituents include alkoxy, halo, etc. see the list in page 3, lines 26-28) attached at the 5-position, which phenyl is further substituted with -A-R₅. The reference also discloses a species falling within the above genus, see e.g., the compound of Example 34 which is depicted below for convenience:



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Claim 46 of the instant application includes the species N-(4-(4-amino-7-cyclopentyl-7H-pyrrolo[2,3-d]pyrimidin-5-yl)-2-chlorophenyl)-1-benzenesulfonamide (lines 12-13) which is depicted below for convenience:



As can be seen from the above two structural formula, the only difference between the reference compound and the instantly claimed compound is the optional substituent at the 2-position. The reference discloses a methoxy substituent and further teaches the equivalency of alkoxy, halogen, etc. as all these are taught to be alternatives as substituents on the phenyl ring. Therefore, the reference clearly suggests the instantly claimed compounds. Further, both the reference compounds as well as the instantly claimed compounds are disclosed to be useful as tyrosine kinase inhibitors.

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Applicant cites *In re Baird* and argues that the genus of the reference is not sufficient to establish a *prima facie* case of obviousness. This is not found to be persuasive because the decision in *Baird* was based on a big genus encompassing millions of compounds vs. a small number of claimed species, “[A] disclosure of millions of compounds does not render obvious a claim to three compounds, particularly when that disclosure indicates a preference leading away from the claimed compounds.” 29 USPQ2d 1552. However, the instant case involves a reference teaching genus/species vs. claimed species and not a broad genus vs. a small number of species. More specifically, as illustrated above, the reference provides a representative compound (Example 34) and further provides alternative substituents as structural variants. The instantly claimed compound is an obvious modification of the reference representative compound because in the instant compound a single substituent has been replaced by a reference suggested alternative. Therefore, motivation exists to modify the prior art compounds to prepare the instantly claimed compounds with the reasonable expectation of obtaining compounds having similar properties.

Applicant cites *In re Jones* to overcome the obviousness rejection. However, *Jones* dealt with the obviousness of a particular claimed ammonium salt based on a generic teaching of “substituted ammonium salts” with no Markush recitation for particular moiety, aminoethoxy ethanol, the salt on appeal. Secondary references applied in *Jones* were deemed not properly combinable with the generic disclosure in the primary reference since the references were not all from the same art area. Unlike the situation in *Jones*, the instantly claimed compounds are

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obvious structural variants of compounds expressly taught by the reference. As explained above, the reference generically discloses all the elements of the instantly claimed genus and further, provides an example that differs only by a single substituent. Thus, the reference provides sufficient motivation for the ordinary artisan to modify the reference compounds to arrive at the instantly claimed compounds because one of ordinary skill in the art only needs to change the position of the substituent to arrive at the instant invention. Such modification would have been obvious, absent a showing of unexpected results.

2. Claims 6 and 7 are rejected under 35 U.S.C. 102(a) as being anticipated by Calderwood et al., WO 98/41525, for the reasons provided in the previous office action which are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that the reference species have a methoxy or hydroxy substituent on ring A and the instant claims do not list 'methoxy' or 'hydroxy' among the substituents for Ring A. It is agreed that the instant claims do not recite the terms 'methoxy' and 'hydroxy' as substituents for ring A, however, the claims include R_c as a substituent on ring A, and R_c is defined as $-W-(CH_2)_t-O-alkyl$ or $-W-(CH_2)_t-OH$ wherein W can be a bond and t can be zero, and therefore, the variable R_c includes the terms 'methoxy' and 'hydroxy', which are the substituents on phenyl ring for reference compounds.

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3. Claims 6-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Calderwood et al., U.S. Patent No. 6,001,839, for the reasons provided in the previous office action which are incorporated hereby reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that the reference species have a methoxy or hydroxy substituent on ring A and the instant claims do not list 'methoxy' or 'hydroxy' among the substituents for Ring A. It is agreed that the instant claims do not recite the terms 'methoxy' and 'hydroxy' as substituents for ring A, however, the claims include R_c as a substituent on ring A, and R_c is defined as $-W-(CH_2)_t-O-alkyl$ or $-W-(CH_2)_t-OH$ wherein W can be a bond and t can be zero, and therefore, the variable R_c includes the terms 'methoxy' and 'hydroxy', which are the substituents on phenyl ring for reference compounds.

4. Claims 1-8, 10 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calderwood et al., WO 98/41525, for the reasons provided in the previous office action which are incorporated hereby reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. The reasons of traversal are similar to those of the rejection of claim 46, all of which have been answered above.

Applicant's arguments based on *In re Grabiak* have been fully considered but they were not deemed to be persuasive. The situation in *Grabiak* was different from the instant application because the references in that case did not provide evidence to substitute sulfur for oxygen, and

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therefore, the court concluded that 'there must be adequate support in the prior art for the ester/thioester change in structure, in order to complete the *prima facie* case'. The instant scenario is different because the reference clearly teaches the equivalency between the various substituents in that any of the substituent from the list provided can be selected to be substituted on the phenyl group and further the reference provides examples of such substituted phenyl groups and thus, provides sufficient motivation to one of ordinary skill in the art to use any of the substituents on the phenyl group. Therefore, for all the reasons of record, in the absence of unexpected properties, it is maintained that the instantly claimed compounds are obvious over the prior art disclosure.

The following rejections are necessitated by the amendment:

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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1. Claims 1-5, 8, 10 and 47 are rejected under 35 U.S.C. 102(a) as being anticipated by Calderwood et al., WO 98/41525 (published September 24, 1998). The instantly claimed compounds read on the compounds of the reference, see formula (I) and the species, e.g., page 14, lines 9-14, 22-23, etc. The instantly amended claim 1 includes compounds wherein ring A can be substituted by R_c which is defined to be $-W-(CH_2)_t-O\text{-alkyl}$ or $-W-(CH_2)_t-OH$. The above groups represent alkoxy or hydroxy respectively wherein W is a bond and t is 0 and therefore, the substituents on ring A of the instant claims includes methoxy and hydroxy.

2. Claims 1-5, 8, 10 and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Calderwood et al., U.S. Patent No. 6,001,839 (filed March 17, 1998). The instantly claimed compounds read on the compounds of the reference, see formula (I) and the species, e.g., col. 10, lines 5-15, 26-27, 30-31, etc. The instantly amended claim 1 includes compounds wherein ring A can be substituted by R_c which is defined to be $-W-(CH_2)_t-O\text{-alkyl}$ or $-W-(CH_2)_t-OH$. The above groups represent alkoxy or hydroxy respectively wherein W is a bond and t is 0 and therefore, the substituents on ring A of the instant claims includes methoxy and hydroxy.

Allowable Subject Matter

Claim 52 is allowed. The closest references of record, US'839 or WO'525 do not teach or fairly suggest the instantly claimed species, wherein the second phenyl ring is substituted with a 2-OCF₃. The reference does not teach that the phenyl ring of R₅ be substituted with a haloalkoxy group.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'Deepak Rao', with a stylized flourish at the end.

Deepak Rao
Primary Examiner
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September 24, 2003